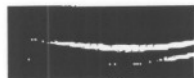


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MedStar Health

Michael C. Rogers
Executive Vice President
Corporate Services

June 10, 2005

Robert E. Nicolay, CPA
Chairman,
Certificate of Need Task Force
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Commissioner Nicolay:

I am pleased to submit comments to the Maryland Health Care Commission (MHCC) Certificate of Need (CON) Task Force on behalf of our member hospitals and health care providers that include among others: Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, Union Memorial Hospital and, MedStar VNA in Maryland; and Georgetown University Hospital, National Rehabilitation Hospital and Washington Hospital Center located in the District of Columbia.

MedStar Position on Certificate of Need Regulation

We appreciate the opportunity to offer comments on our vision for the certificate of need program in Maryland. In November 1999, MedStar Health issued a position statement supporting the CON model of regulation because of its benefits in ensuring access to quality and cost effectiveness services. We believe the CON program remains the state's most comprehensive regulatory tool for implementing health policies directed at:

- Ensuring health care service development is consistent with state health goals and policies;
- Ensuring financial and geographic access of services to all Marylanders;
- Ensuring optimal quality of among Maryland providers; and
- Ensuring that health care providers are accountable to the public.

In the attached statement we offer our perspective on the existing certificate of need program and the principles that should guide the reform efforts being undertaken by the Task Force.

We at MedStar Health are committed to working with the Task Force as you embark on setting the future course for health care in the State and we thank you for this opportunity to comment.

Sincerely,

Michael C. Rogers, Executive Vice President
Corporate Services

ATTACHMENT

cc: John P. McDaniel
Kenneth A. Samet
William L. Thomas, M.D.
Michael Curran
Christine Swearingen

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Position on Maryland's Certificate of Need Program and Principles to Guide Reforms

Over the years, Maryland's health care regulatory system has made many contributions to the delivery of care, including containing run-away costs, and promotion of access, affordability and accountability. Many tenets of the 30-year-old system still allow Marylanders to enjoy high quality, affordable health care. It is however, a highly complex system that lacks the flexibility needed in today's changing health care environment.

As we struggle to adjust to change, we have seen priorities collide and systems become overburdened. Issues such as: a lack of coordination in formulating and implementing state health policy decisions; the use of outdated regulations; fragmented data collection; lack of focus in assuring quality and identifying community needs; and the increasing costs and burdens of existing regulations on health care – all have raised concerns and pose difficult challenges.

Planning Issues

When Certificate of Need (CON) laws were being written across the country in the 1970s, they were primarily a mechanism to control rising health care costs by keeping hospitals and other providers from expanding unnecessarily. In Maryland, CON regulations were implemented as such a mechanism, as well as a way to ensure adequate access and quality. The question before us today is whether CON is still the best way to achieve the goals of cost efficiency, quality and access? Or, is the marketplace and managed care pressures better suited to this task?

CON should be preserved where it has value and eliminated where it no longer serves a purpose or has a minimal impact on improving access to quality and cost effectiveness of the overall delivery system. Over the years, the CON process has proved to be cumbersome and costly to maintain. Because of the unwieldy process that healthcare providers must follow to make even the most basic adjustments, it has become increasingly difficult for them to make quick and timely decisions in response to changing community needs.

MedStar Health Supports Certificate of Need Program

MedStar believes an effective CON program remains the state's most comprehensive regulatory tool for implementing health policies directed at:

- Ensuring health services development is consistent with state health goals and policies;
- Ensuring financial and geographic access of services to all Marylanders;
- Ensuring optimal quality among Maryland providers;
- Ensuring cost effectiveness of health care services;
- Ensuring that health care providers are accountable to the public; and
- Providing balance between the mandated policy goals of the Health Service Cost Review Commission which focuses on cost and the financial viability of Maryland's hospitals and the goals of access and quality which are the hallmark of the Maryland Health Care Commission.

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Ensuring Healthcare Service Development is Consistent with State Health Goals and Objectives

Essentially, the CON process requires hospitals and health care providers to look prospectively at who comprises their potential patient base and at the needs of those patients. Certificate of Need regulations are not, and never have been, efforts to punish providers. They are instead efforts to protect patients by ensuring that offered services are necessary (to avoid costly, unneeded programs).

Services requiring CON approval must meet certain criteria and standards specified in the State Health Plan (SHP), a policy document that assesses residents' health care needs and required health resources. The CON process creates a system of incentives to encourage providers to design services that best meet the public's health care needs. The process is particularly helpful in encouraging services for the elderly, poor and minority populations that, for pure financial reasons, otherwise might not be developed. The CON process is the most important regulatory mechanism at the State's disposal, which incentivizes private sector providers to pursue public policy objectives.

Ensuring Financial and Geographic Access

CON's mandatory requirements and preference incentives also help ensure geographic and financial access for all members of the community. Historically, the Commission has given preferences to providers who develop services in geographic areas with the greatest need. Likewise, preferences are given to providers whose proposals address non-financial barriers to obtaining care; e.g., clinic programs with extended hours of operation to make them more accessible to those who work.

The CON process also ensures financial access to services by requiring minimum uncompensated care commitments. One of Maryland's great health care strengths is its systematic commitment to providing health care for all those in need. Elimination of the CON process could diminish that commitment.

Ensuring Optimal Quality

In regard to quality, the CON process helps maintain high quality by ensuring that programs meet minimum structural quality and process standards, promoting minimum volume requirements, and by requiring collection and dissemination of data to monitor quality.

Minimum structural and process standards for new programs and services increase the likelihood that programs produce good patient outcomes. This is particularly important for complex, specialized and resource-intensive services such as organ transplants, burn centers, open-heart surgery, obstetrics and neonatal care that require both significant capital investments and highly skilled medical professionals. Requiring those programs to demonstrate that they will meet established structural and process standards before a program is initiated is a crucial aspect of the CON process that ensures the quality of Maryland's health care providers.

Requiring that certain programs meet minimum volume standards not only addresses whether programs are needed but also guarantees that programs are handling enough cases to maintain the proficiency of their staff on an ongoing basis.

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By design, the CON process limits the number of providers of specialized services in order to concentrate specialized expertise and resources to promote higher case volumes—and the higher levels of quality this produces.

The quality-volume relationship is an important one that directly relates to the value of CON. Research shows an inverse relationship between a hospital's volume of certain specialized surgical procedures and poor surgical outcomes. In other words, high volume programs have lower mortality and morbidity rates. Research on this issue has led to professionally established minimum volume guidelines.

If CON, which requires careful planning and the establishment of only necessary programs, were eliminated for specialized services, then Maryland could experience a proliferation of new, low-volume, lower quality programs. Most specialized services in Maryland meet or exceed optimal volume threshold recommendations, which contribute to the high quality of programs in the State. Proliferation of new, unnecessary programs could jeopardize the quality of care at these existing programs by draining their patient volume and diluting their resources.

It is also important to note that the CON process provides the regulatory basis for collecting utilization, clinical outcome and financial data, which play an essential role in planning for responsible health care development.

Ensuring Cost Effective Healthcare Services

As the elimination of some, if not all, CON requirements are debated; consideration must also be given to the cost containment effect of CON regulations. CON regulations prevent unnecessary expansion of costly medical programs and duplication of expensive services and technology; thus, it helps keep health care costs down. Health care providers must demonstrate that their proposals for new services and capital expenditures are cost effective and will not have an adverse economic or programmatic impact on existing providers. This process discourages applicants from pursuing ill-conceived projects. Many health care projects do not see the "light of day" as a result of the existence of the CON process. Though difficult to quantify, the CON process has a chilling effect on the development of unnecessary services.

Additionally, the concentration of high cost specialized services in a few regional centers as provided under CON leads to more efficient and cost effective programs due to economies of scale, more proficient staff and better technology, thus containing costs. The elimination of CON could potentially lead to the introduction of additional unnecessary services which would drain resources from the larger regional centers and make it inefficient for these providers to support training, research, and uncompensated care.

Ensuring Public Accountability

The CON regulatory process exists as a means of public oversight for health care planning and policy throughout the State. Both public and private providers must publicly detail their proposals for new programs and services and receive approval before undertaking those investments. Public accountability encourages thoughtful, cost effective and necessary projects that will enhance the health care of the community. Additionally, the CON process affords the opportunity for providers and the public to comment and question applicants for new programs and services and permits a public decision-making process that allows for the selection of the best project among alternative proposals that ensures institutional needs are balanced with community needs.

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Proposed Framework for Reforming Maryland's Certificate of Need Program

Identifying the principles that should set the framework for reforming Maryland's certificate of need program is a critical first step in reaching consensus on reforms for Maryland's Certificate of Need program. Some of the principles that should be considered in the debate on certificate of need regulatory reform include:

- *FAIRNESS - Similar classes of providers and services should be subject to similar regulatory restrictions and freedoms.*

Currently exemptions, waivers and other regulatory actions create opportunities – and even incentives – for health care providers to establish services outside the confines of existing regulations, giving them a distinct advantage over competitors and creating inconsistent oversight. As new care settings grow in importance, more fair and consistent regulatory oversight is needed.

- *REGIONALISM – Regulations must recognize that health care markets are no longer delineated by municipal and state boundaries.*

In our ever-evolving economy, service areas – particularly for health care – are no longer autonomous, neatly defined cities or counties or even states. The emergence of regional markets that extend beyond traditional boundaries are a fact of economic life and require a reasoned regulatory response and should be coordinated with other jurisdictions.

- *RATIONAL PLANNING – Certificate of Need regulations should focus on high-cost institutional or specialized health care services and certain community-based services to ensure access and quality of programs.*

Maryland's CON process is an important mechanism for ensuring equitable access to health care for the benefit of all individuals and communities. While in many ways the process has served Maryland well, in many other ways it has stifled growth and created impediments that are contrary to its goal of ensuring quality, efficient and accessible health care. Certificate of Need regulations still have an important role to play, but that role should be confined to areas where they will achieve the most benefit in maintaining quality, access and hold down costs.

- *RESPONSIBILITY – The costs of providing uncompensated care and graduate medical education should be broadly shared.*

Providers of health care have responsibilities beyond the walls of their facilities. Care for those who cannot afford it is one of those responsibilities, along with the education of future healthcare professionals. These are societal costs. But all health care providers and payors do not help shoulder this burden, leaving those who do with a disproportionate share of these costs. Medical education and care for the uninsured are not commitments to be avoided but responsibilities to be met – by all.

Maryland has long been a leader in setting new standards in health care. By working together as an industry, we can identify the priorities that will guide effective, meaningful regulatory reform in our State. We believe that these principles provide our entire health care community with a solid foundation on which to examine our future reforms.

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- **OBJECTIVITY** – *Objective data and evidence-based assumptions must inform certificate of need policies and decisions.*

Objective population-based need methodologies and evidenced-based assumptions should be the central core for certificate of need policies and certificate of need determinations. There is a movement to relegate population-based need projections to a lesser role and reliance on more subjective "community-benefits standards" in determination of need. For instance, the Commission has abandoned the need projections for obstetric services and open-heart surgery and will consider and may approve new programs despite objective evidence of declining or stable need. Abandoning objective population-based need methodologies for more subjective need determination methodologies undermines the certificate of need process and makes the process more of a political process rather than a process driven by facts and data.

- **UNIFIED REGULATORY MODEL** – *The Commission should embrace an overall regulatory model.*

Previous reviews of the certificate of need program has looked at the appropriate certificate of need regulatory approach on a service-by-service basis. That approach yielded a disparate and, at times contradictory set of regulations without a unifying regulatory theme. We recommend that the Commission adopt a set of overarching and unifying principles for the certificate of need program that can be adjusted for the unique circumstance of a particular service or group of services based on the clearly articulated principles. Currently there are myriad of exemptions, exceptions, preferences and approaches to service regulation.

- **TIMELINESS AND PREDICTABILITY OF PROCESS** – *The current review process needs to be timely and predictable.*

The certificate of need program burdened by increasing workload is unable to meet statutorily defined timeframes and slows the regulated industry's response to changes in the dynamic health care field.

- **CURRENCY OF REGULATIONS**- *Certificate of need program regulation is slow to respond to changes in the science of health care.*

There is a need for certificate of need regulations to be kept current in response to the dynamic health care environment. There is often a lag time between changes in science and adoption or modification of CON regulations.

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Process/Procedural Reforms To Consider for Maryland's Certificate of Need Program

As the CON Work commences its review of Maryland's Certificate of Need review, we suggest consideration be given to the following:

1. How objective population-based need methodologies will be used in the CON process vs. more subjective need determination approaches, e.g., "community benefits standards".
2. Reviewing all exemptions/review preferences for continued relevance and consistency and fairness across the continuum of health care providers.
3. Re-evaluating the geographic bases for need determinations—political jurisdictions, e.g., county, regional areas or zip code defined natural health care market areas, etc.
4. Considering narrowing the focus of regulations/reviews to services/capital expenditures with major system impacts as a means to reducing workload and effectiveness of the regulatory system.
5. Evaluating mechanisms to improve timeliness and predictability of review processes to enhance the ability of providers to implement new services or expansion of new services in a timely manner to meet needs of their communities.
6. Considering differentiated levels or intensity of review by project type or project impact for instance to include administrative or expedited reviews for certain types of projections such as:
 - Infrastructure replacements
 - IT Technology
 - New Services
 - Capital expenditures > \$7.5 million, etc.
7. Considering increasing the dollar threshold to \$7.5 million or higher to reduce number of reviews and focus on projects with greater health system impact.
8. Considering increasing exemptions for a broader range of projects.
9. Eliminating CON review of all facility closures and replace with a notification procedure.
10. Eliminating duplicate standards covered by other state agencies or accrediting bodies in CON reviews, e.g. quality standard of licensing agencies, etc.

Conclusion

With Maryland's health care regulatory structure undergoing a number of changes, it makes sense to approach reforms carefully. Alternatives or different approaches to the current CON Program do exist and many bring benefits to the regulation of health care in Maryland, but we believe the State will be hard pressed to find a regulatory tool that ensures access, quality, and cost-effectiveness in the same manner as CON. CON regulations have served Maryland well—creating a system of well-performing health care providers, which serve the community's needs.

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CON is the most comprehensive tool to implement state health policy, and we should give contemplated changes to the current system careful thought. We must not simply think about what is wrong with CON, but also think about what is right with the CON process and how we can make it work better where it works and eliminate or change the provisions that do not work.

Make no mistake about it, MedStar Health is firmly committed to the continuation of an effective Certificate of Need program and looks forward to being an active participant in the review effort of the CON Task Force.

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